Appendix A: Claims from copending U.S. Patent Application No. 10/744,420

1. A collagenous biomaterial medical device comprising a sponge material formed from particulate submucosa.

2. The medical device of claim 1 formed by a process including freezing and drying a material including particulate submucosa and water.

3. The medical device of claim 1 also comprising at least one pharmacologic agent disposed on the sponge material.

4. The medical device of claim 1 wherein the sponge material is crosslinked with a crosslinking agent.

5. The medical device of claim 4 wherein the crosslinking agent is a carbodiimide.

6. The medical device of claim 4 wherein the crosslinking agent is glutaraldehyde.

7. The medical device of claim 1 wherein the particulate submucosa retains at least one biotropic agent.

8. The medical device of claim 1 wherein the at least one biotropic agent is a proteoglycan, a glycosaminoglycan, or a growth factor.

9. The medical device of claim 1 wherein the particulate submucosa includes a proteoglycan, a glycosaminoglycan and a growth factor.

10. The medical device of claim 3 wherein the pharmacologic agent includes one or more growth factors, proteins, proteoglycans, glycosaminoglycans, physiological compatible minerals, antibiotics, chemotherapeutic agents, enzymes, drugs, and hormones.

11. The medical device of claim 1, wherein said submucosa is selected from intestinal submucosa, urinary bladder submucosa, and stomach submucosa.

12. The medical device of claim 11, wherein said submucosa is small intestinal submucosa.

13. The medical device of claim 12, wherein said small intestinal submucosa is porcine.

14. A method for forming a collagenous biomaterial medical device, comprising: providing a material including particulate submucosa and water; freezing said material; and drying said material.

15. The method of claim 14, wherein said particulate submucosa retains at least one biotropic agent.

16. The method of claim 15, wherein said biotropic agent is a proteoglycan, a glycosaminoglycan, or a growth factor.

17. The method of claim 14, wherein the submucosa is selected from intestinal submucosa, urinary bladder submucosa, and stomach submucosa.

18. The method of claim 17, wherein the submucosa is small intestinal submucosa.

Appendix A (continued)

19. The method of claim 18, wherein the small intestinal submucosa is porcine.

20. A method for forming a collagenous biomaterial medical device, comprising: providing a material including a particulate collagenous matrix and water, said particulate collagenous matrix obtained from a tissue source therefor and retaining biotropic agents including a proteoglycan, a glycosaminoglycan and a growth factor; freezing said material; and drying said material.

Appendix B: Claims from co-pending U.S. Patent Application No. 10/811,343

1. A graft prosthesis comprising: a purified, collagen-based matrix structure removed from a submucosa tissue source, said purified structure having a contaminant level making said purified structure biocompatible.

2. The graft prosthesis of claim 1, wherein said purified structure has an endotoxin level of less than 12 endotoxin units per gram.

3. The graft prosthesis of claim 2, wherein said endotoxin level is less than 10 endotoxin units per gram.

4. The graft prosthesis of claim 3, wherein said endotoxin level is less than 5 endotoxin units per gram.

5. The graft prosthesis of claim 4, wherein said endotoxin level is less than 1 endotoxin unit per gram.

6. The graft prosthesis of claim 1, wherein said purified structure has a bioburden level of less than 2 colony forming units per gram.

7. The graft prosthesis of claim 6, wherein said bioburden level is less than 1 colony forming unit per gram.

8. The graft prosthesis of claim 7, wherein said bioburden level is less than 0.5 colony forming units per gram.

9. The graft prosthesis of claim 1, wherein said purified structure has a nucleic acid content level of less than 10 micrograms per milligram.

10. The graft prosthesis of claim 9, wherein said nucleic acid content is less than 2 micrograms per milligram.

11. The graft prosthesis of claim 1, wherein said purified structure has a virus level of less than 500 plaque forming units per gram.

12. The graft prosthesis of claim 11, wherein said virus level is less than 100 plaque forming units per gram.

13. The graft prosthesis of claim 12, wherein said virus level is less than 1 plaque forming unit per gram.

14. The graft prosthesis of claim, wherein said purified structure has a processing agent level of less than 100,000 parts per million per kilogram.

15. The graft prosthesis of claim 14, wherein said processing agent level is less than 1,000 parts per million per kilogram.

16. The graft prosthesis of claim 15, wherein said processing agent level is less than 100 parts per million per kilogram.

17. The graft prosthesis of claim 1, wherein said purified structure has a fungus level of less than 2 colony forming units per gram.

Appendix B (continued)

18. The graft prosthesis of claim 17, wherein said fungus level is less than 1 colony forming units per gram.

19. The graft prosthesis of claim 18, wherein said fungus level is less than 0.5 colony forming units per gram.

20. The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source.

21. The graft prosthesis of claim 1, wherein said purified structure comprises a disinfected and delaminated submucosa tissue source.

22. The graft prosthesis of claim 1, wherein said purified structure comprises a disinfected and then delaminated submucosa tissue source.

23. A graft prosthesis comprising: a purified, collagen-based matrix structure removed from a submucosa tissue source, said purified structure having an endotoxin level of less than 12 endotoxin units per gram.

24. A graft prosthesis comprising: a purified, collagen-based matrix structure removed from a submucosa tissue source, said purified structure having a nucleic acid content level of less than 2 micrograms per milligram.

25. A graft prosthesis comprising: a purified, collagen-based matrix structure removed from a submucosa tissue source, said purified structure having a virus level of less than 500 plaque forming units per gram.

26. A graft prosthesis comprising: a purified, collagen-based matrix structure removed from a submucosa tissue source, said purified structure having a processing agent level of less than 100,000 parts per million per kilogram.

27. A method for obtaining a collagen-based matrix from a submucosa tissue source, comprising: treating the submucosa tissue source with a disinfecting agent to provide a disinfected submucosa tissue source; and removing the collagen-based matrix from the disinfected submucosa tissue source.

28. The method of claim 27, wherein the submucosa tissue source is from an alimentary tract of a mammal.

29. The method of claim 28, wherein the mammal is a pig.

30. The method of claim 29, wherein the submucosa tissue source is from the small intestine of a pig.

31. The method of claim 27, wherein the disinfecting agent is an oxidizing agent.

32. The method of claim 27, wherein the disinfecting agent is a peroxy compound.

33. The method of claim 32, wherein the disinfecting agent is an organic peroxy compound.

34. The method of claim 33, wherein the disinfecting agent is a peracid.

Appendix B (continued)

35. The method of claim 34, wherein the peracid is selected from the group consisting of peracetic acid, perpropionic acid and perbenzoic acid.

36. The method of claim 35, wherein the peracid is peracetic acid.

37. The method of claim 34, wherein said treating includes treating the submucosa tissue source with a medium containing an alcohol and the peracid.

38. The method of claim 37, wherein the alcohol has one to about six carbon atoms.

39. The method of claim 38, wherein the alcohol is selected from the group consisting of ethanol, propanols, and butanols.

40. The method of claim 39, wherein the alcohol is ethanol.

41. The method of claim 40, wherein the medium is an aqueous ethanol solution containing from about 0.1% to about 0.3% by volume peracetic acid.

42. The method of claim 34, wherein said treating includes treating the submucosa tissue source with a medium containing the peracid and having a pH of about 2 to about 6.

43. The method of claim 42, wherein the medium has a pH of about 2 to about 4.

44. The method of claim 43, wherein the peracid is peracetic acid, and the medium contains about 0.1% to about 0.3% by volume of peracetic acid.

45. A method for obtaining a collagen-based matrix from a submucosa tissue source, comprising: providing a submucosa tissue source which has been treated with a disinfecting agent; and removing the collagen-based matrix from said submucosa tissue source.

46. The method of claim 45, wherein said submucosa tissue source is from a small intestine.

47. The method of claim 46, wherein said disinfecting includes treating the submucosa tissue source with an oxidizing agent.

48. The method of claim 47, wherein said treating includes contacting the submucosa tissue source with an aqueous medium containing the oxidizing agent.

49. The method of claim 47, wherein said treating includes contacting the submucosa tissue source with an aqueous medium containing a peroxy compound.

50. The method of claim 49, wherein the peroxy compound is a peracid.

51. The method of claim 50, wherein the peracid is peracetic acid.

52. The process of claim 51, wherein the medium comprises an alcohol.

53. The process of claim 52, wherein the alcohol is ethanol.

54. The method of claim 51, wherein the small intestine is from a pig.

Appendix B (continued)

55. A composition comprising: a collagen-containing structure removed from a tissue source initially containing said structure and other tissue, said collagen-containing structure having an endotoxin level of no greater than 12 endotoxin units per gram.

56. The composition of claim 55, wherein said collagen-containing layer is submucosa and said tissue source is small intestine.

57. The composition of claim 56, wherein said tissue source is pig small intestine.

58. The composition of claim 55, wherein said endotoxin level is less than 10 endotoxin units per gram.

59. The composition of claim 58, wherein said endotoxin level is less than 5 endotoxin units per gram.

60. The composition of claim 50, wherein said endotoxin level is less than 1 endotoxin unit per gram.

61. The composition of claim 60, wherein said endotoxin level is less than 0.5 endotoxin units per gram.

62. A purified collagen-containing matrix obtained from a mammalian tissue source, said matrix comprising mammalian tela submucosa and residual contaminants from said mammalian tissue source, said structure obtainable by a process which comprises disinfecting said mammalian tissue and then removing said structure from the disinfected mammalian tissue.

63. The composition of claim 62 wherein said disinfecting includes contacting the mammalian tissue source with an aqueous solution containing a peracid.

64. The composition of claim 63 wherein the peracid is peracetic acid.